

1053682-6AU.644

JC09 Rec'd PCT/PTO 03 JUN 2009

RTO/SB/DRB (08-03)

PTO/SB/08a (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031

Approved for use through 07/31/2006. GMB 0851-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(Use as many sheets as necessary)</p>				<p><b>Complete if Known</b></p>	
<p>Application Number</p>		<p>03-29-2001</p>		<p>Filing Date</p>	
<p>First Named Inventor</p>		<p>Banchereau, et al.</p>		<p>Art Unit</p>	
<p>Examiner Name</p>		<p></p>		<p></p>	
Sheet	1	of	4	Attorney Docket Number	BHCS:2000

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner \_\_\_\_\_ Date \_\_\_\_\_

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "Applicant's unique citation designation (optional)." See "Kind Codes of USPTO Citation References" at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. "Enter Office that issued the document, by the two-letter code (WIPO Standard ST.13)." For earlier patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. "Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible." "Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./

JC09 Rec'd PCT/PTO 03 JUN 2005

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	Banchereau, et al.
				Art Unit	
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	BHCS:1028

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		THURNER, et al. Vaccination with MAGE-3A 1 peptide-pulsed mature, monocyte-derived dendritic cells expands scientific cytotoxic T cells and induces regression of some metastases in advance stage IV melanoma. <i>J Exp Med.</i> 1999, Vol. 190, No. 11, Pages 1669-1678.			
		MACKENSEN, et al. Phase I study in melanoma patients of a vaccine with peptide-pulsed dendritic cells generated in vitro from CD34(+) hematopoietic progenitor cells. <i>Int J Cancer.</i> 2000, Vol. 86, No. 3, Pages 385-392.			
		NESTLE, et al. Vaccination of melanoma patients with peptide- or tumor lysate pulsed dendritic cells. <i>Nat. Med.</i> 1998, Vol. 4, No. 3, Pages 328-332.			
		BANCHEREAU et al. Immune and clinical responses in patients with metastatic melanoma to CD34+ progenitor-derived dendritic cell vaccine. <i>Cancer Res.</i> 2001, Vol. 61, pages 6451-6458.			
		BERARD, et al. Cross-priming of naïve CD8 T cells against melanoma antigens using dendritic cells loaded with killed allogenic melanoma cells. <i>J Exp Med.</i> 2000, Vol. 192 No. 11, Pages 1535-1543.			
		SIENA, et al. Massive ex vivo generation of functional dendritic cells from mobilized CD34+ blood progenitors from anticancer therapy. <i>Exp Hematol.</i> 1995, Vol. 23, No. 14, Pages 1463-1471.			
		ELJAAFARI, et al. Generating of stable monocyte-derived dendritic cells in the presence of high concentration of homologous or autologous serum: influence of extra-cellular pH. <i>Hum Immunol.</i> 1998, Vol. 59, No. 10, Pages 625-634.			
		ALVING, et al. Liposomes as carriers or peptide antigens: induction of antibodies and cytotoxic T lymphocytes to conjugated and unconjugated peptides. <i>Immunol. Rev.</i> 1995, Vol. 145, Pages 5-31.			
		HSUEH, et al. Correlation of specific immune responses with survival in melanoma patients with distant metastases receiving polyvalent melanoma cell vaccine. <i>J. Clin. Oncol.</i> 1998, Vol. 16, No. 9, pages 2913-2920.			
		HARTUNG, et al. On tests of the overall treatment effect in meta analysis with normally distributed responses. <i>Stat Med.</i> 2001, Vol. 20, Pages 1771-1782.A			
		GROSS, et al. Monitoring the immunological status of patients receiving BCG therapy of malignant disease. <i>Cancer.</i> 1976, Vol. 37, No. 5, Pages 2183-2193.			

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached. The English language translation is required by 37 CFR 1.97 and 1.98. The English language translation is required to obtain or maintain a benefit for the purpose which is to file (and by the USPTO to process) an application. Consideration is governed by 35 U.S.C. 122 and 37 CFR 1.98. The collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

Application Number

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

BHCS:1028

## NON PATENT LITERATURE DOCUMENTS

Examiner initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	T <sup>2</sup>
		RATTA M, et al. Generation and functional characterization of human dendritic cells, derived from CD34 cells mobilized from peripheral blood: comparison with bone marrow CD34+ cells. <i>Br J Haematol</i> . 1998, Vol. 101 No. 4, Pages 755-765	
		CAO, et al. In vitro generation of dendritic cells from human blood monocytes in experimental conditions compatible for ex vivo cell therapy. <i>J Hematother. Stem Cell Res.</i> 2000, Vol. 9, No. 2, Pages 183-194.	
		ARDECHINA, et al. A clinically applicable method for ex vivo generation of antigen-presenting cells from CD34+ progenitors. <i>Vox Sang.</i> 2000, Vol. 79, No. 1, Pages 46-52.	
		KNAPP, et al. Improved tests for random effects of meta-regression with a single covariate. <i>Stat. Med.</i> 2003, Vol. 22, Pages 2693-2710.	
		KOWALKOWSKI, et al. Ex vivo generation of dendritic cells from the CD34+ cells in gas-permeable containers under serum-free conditions. <i>J. Hematother.</i> 1998, Vol. 7, No. 5, Pages 403-411.	
		BORRAS, et al. Dendritic cells can be successfully generated from CD34+ cord blood cells in the presence of autologous cord blood plasma. <i>Bone Marrow Transplant.</i> 2000, Vol. 26, No. 4, pages 371-376.	
		SKEA, et al. Adjuvant-independent induction of immune responses by antibody-mediated targeting of protein and peptide antigens. <i>Reg. Immunol.</i> 1992, Vol. 143, No. 5, pages 568-572.	
		CARAYANNOTIC, et al. Delivery of synthetic peptides by anti-class II MHC monoclonal antibodies induces specific adjuvant-free IgG responses in vivo. <i>Mol. Immunol.</i> 1988, Vol. 25, No. 9, Pages 907-911.	
		BAIU, et al. Modulation of the humoral immune response by antibody-mediated antigen targeting to complement receptors and Fc receptors. <i>J. Immunol.</i> 1999, Vol. 162, pages 3125-3130.	
		SCHJETNE, et al. Cutting edge: Ling between innate and adaptive immunity: Toll-like receptor 2 internalizes antigen for presentation to CD4+ T cells and could be an efficient vaccine target. <i>J Immunol.</i> 2003, Vol. 171, Pages 32-36.	
		CHAKRABORTY, et al. Immunization with a tumor-cell-lysate-loaded autologous-antigen-presenting-cell-based vaccine in melanoma. <i>Cancer Immunol. Immunother. Ember.</i> 1998, Vol. 47, Pages 58-64.	

Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./

Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<i>Application Number</i>	
				<i>Filing Date</i>	
				<i>First Named Inventor</i>	Banchereau, et al.
				<i>Art Unit</i>	
				<i>Examiner Name</i>	
(Use as many sheets as necessary)					
Sheet	4	of	4	Attorney Docket Number	BHCS:1028

#### NON-PATENT LITERATURE DOCUMENTS

Examiner Signature	/Gerald Ewoldt/	Date Considered	02/16/2010
-----------------------	-----------------	--------------------	------------

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**Applicant's unique citation designation number (optional):**  **Applicant is to place a check mark here if English language Translation is attached.**

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.E./